

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Docket No. 33103
SMITH, Mark W.L., et al.	Confirmation No.: 1929
Serial No.: 10/707,930	Group Art Unit No. 3772
Filed: January 26, 2004	Customer No.: 23589
ABOVE KNEE SHRINKER	Examiner: PHAM, Huong Q.

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION OF MARK W.L. SMITH

Comes now Mark W.L. Smith and declares as follows:

1. I am currently the President of Knit-Rite, Inc. of Kansas City, Kansas ("Knit-Rite").

As President of Knit-Rite, I am familiar with the history of above-knee shrinker technology and products.

2. I am a co-inventor of the present application and Knit-Rite is the assignee of this application. As a co-inventor, I am knowledgeable of the invention disclosed and claimed in the present application.

3. I have also been designated a Certified Prosthetist, Certificate No. CP001731, by the American Board for Certification in Orthotics, Prosthetics & Pedorthics (the "ABC"). As defined by the ABC, a Prosthetist is an allied health professional who is specifically trained and educated to provide or manage the provision of a custom-designed, fabricated, modified and fitted external limb prosthesis to a prosthetic patient, based on a clinical assessment and a physician's prescription, to restore physiological function and/or cosmesis.

LONG-FELT NEED

4. A need has long existed for leg amputees to control or prevent edema following amputation surgery to reduce post-surgical edema, for limb volumetric maintenance, and to give compressive support for pain relief. Moreover, amputees have long sought an above-knee shrinker that is easier to stretch and slip onto the limb. Prosthetic shrinkers must provide substantial limb compression to meet these requirements, but conventional above-knee shrinkers require excessive effort to expand and slip onto the amputated limb and are therefore difficult and often painful to don. Thus, leg amputees have long sought an above-knee shrinker that provides substantial compression of the amputated limb while being easier to slip onto the limb, and the present invention meets this need.

5. The Knit-Rite Compressogrip Above-knee Shrinker product (the "CGAK Shrinker"), which embodies aspects of the invention claimed in the present application, provides sufficient limb compression while being easy to don. In particular, a main portion of the shrinker is first slipped onto the leg, followed by the step of folding over an overhanging portion and slipping the overhanging portion over the main portion. The individual portions can be separately and easily slipped onto the limb, but the portions cooperatively provide the necessary compression when donned.

6. I believe that the unique combination of the U-shaped opening, tubular fabric receptacle, and corespun yarn (as recited in the claims) provides the advantages of reduced manufacturing cost and comfortable shrinker fit. This combination also provides a shrinker that is easy to fit to an amputee by providing an adjustable shrinker length, i.e., by tubular fabric to length. The combination further provides a shrinker that is considerably less expensive to manufacture. Yet further, the combination results in a need for fewer shrinker sizes compared to conventional

shrinkers to cover the expected range of limb sizes. For example, 4 sizes of the CGAK Shrinker can accommodate a range of limb sizes that would be accommodated by 54 sizes of the conventional Knit-Rite above-knee shrinker.

COMMERCIAL SUCCESS

7. The CGAK Shrinker was introduced into the market about five years ago. The CGAK Shrinker has generated a substantial increase in revenue in the past five years. Sales revenue of the CGAK Shrinker in 2008 are expected to be about four times greater than sales revenue in 2003. On a unit basis, sales of CGAK Shrinkers has increased about three and a half times over the same five-year period. Sales revenue for all Knit-Rite above-knee shrinkers has roughly doubled since introduction of the CGAK Shrinker. Over the same five-year period, sales of conventional Knit-Rite above-knee shrinkers dropped by more than half. It is also noteworthy that advertising and sales of Knit-Rite's below-knee shrinkers remained constant over the five-year period, reflecting that Knit-Rite has maintained its market presence for a similar product. That is, Knit-Rite's market presence has not similarly increased for related products. Furthermore, Medicare utilization for purchase of above-knee shrinkers steadily declined in the five-year period, suggesting that overall market demand for above-knee shrinkers has declined.

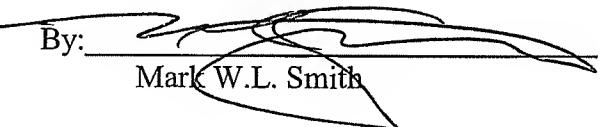
8. Presently, the CGAK Shrinker has a market share of about 33% for the entire market of above-knee shrinkers. Thus, market share for the CGAK Shrinker has grown from zero to about 33% in the past five years. Knit-Rite has several competitors in the above-knee shrinker market. One competitor, Juzo, presently has about a 60% share of the above-knee shrinker market.

9. Advertising and other marketing expenditures for the CGAK Shrinker have been similar to other Knit-Rite products in the five-year period.

10. In comparison to other Knit-Rite products, the CGAK Shrinker has experienced extraordinary commercial success in a short time frame.

11. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 10/17/08

By: 

Mark W.L. Smith